REMARKS

Claims 1, 5, 7-9, 12, 15-17, 19-38, 40-44, 46-53, and 56-62, and 64[1] are pending. Due to a restriction requirement, claims 23, 24, 29-38, 44, 46-53, and 56-62, and 64 are withdrawn from consideration. Claims 1, 5, 7-9, 12, 15-17, 19-22, 25-28, and 40-43 have been examined to the extent that they read on polypeptides. Claims 27 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 20-22 and 25-28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 1, 5, 7-9, 12, 15-17, 19-22, 25-28, and 40 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6, 933,377 ("the '377 patent). Each of these rejections is addressed below.

Claim amendments

Claims 20-28 have been cancelled. No new matter has been added by the present amendment.

Claims 41-43

At page 7 of the action, the Office indicates, "No claim is allowed," but no rejection of claims 41-43, which are not withdrawn from consideration, has been set forth. Absent a rejection, these claims should be indicated as allowable.

Rejection under 35 U.S.C. § 112, first paragraph, written description

Claims 27 and 28 are rejected as failing to comply with the written description requirement. Without assenting to this rejection or surrendering any rights to this subject matter, Applicants have cancelled these claims, thereby rendering this rejection moot.

Withdrawal of this rejection is respectfully requested.

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[1]The Office action states that claims "56-64" are pending. Claim 63, however, was cancelled in the preliminary amendment that was filed May 19, 2006.

Rejection under 35 U.S.C. § 112, first paragraph, enablement

Claims 20-22 and 25-28 are rejected as failing to comply with the enablement requirement. Without assenting to this rejection or surrendering any rights to this subject matter, Applicants have cancelled these claims, thereby rendering this rejection moot.

Withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(e)

Claims 1, 5, 7-9, 12, 15-17, 19-22, 25-28, and 40 are rejected under 35 U.S.C. § 102(e) as being anticipated by the '377 patent. In making this rejection, the Office states:

> US 6,933,377 B2 discloses treating and preventing HIV by administering an HIV gene product(s) wherein the administering includes administering one or more adjuvants that is/are a co-stimulatory molecule, a cytokine, a chemokine, and a growth factor. US 6,933,377 B2 discloses that these adjuvants may include FLT3 ligand, GM-CSF growth factor and chemokine MIP-1α...

Office action, page 6.

To anticipate a claim, a claim must teach each and every element as set forth in the claim. M.P.E.P. § 2131. The identical invention must be shown in as complete detail as shown in the claim, and the elements must be arranged as required by the claim. *Id.*

The present invention is directed, in part, to method that involves administration of an immunogen, Flt3L, and MIP-1α and is partly based on Applicants' discovery of an enhanced immune response that is observed when Flt3L, and MIP-1α are combined with the immunogen. As explained below, this method is not described in the '377 patent.

The '377 patent does not disclose the claimed combination

The Office correctly notes that the '377 patent described administration of HIV gene products. There is however no discussion of administering the combination of Flt3L

and MIP-1α with those gene products. In their review of the '377 patent, Applicants have identified Flt3L as being mentioned twice and MIP-1α as being mentioned once.

The '377 patent (column 18, lines 43-46) states (emphasis added), "In some embodiments, cytokine genes, including but not limited to, IL-2, IL-12, and IL-15, Flt3 ligand, are also introduced to enhance adaptive immune responses."

The '377 patent (column 21, lines 40-48) also states (emphasis added):

> Molecular adjuvants including, but not limited to the following genes or gene products also find use with the vaccines of the present invention: co-stimulatory molecules (e.g., CD80, CD86), proinflammatory cytokines (e.g., IL-1α, TNF-α, TNF-β), T helper 1 cytokines (e.g., IL-2, IL-12, IL-15 and IL-18), T helper 2 cytokines (e.g., IL-4, IL-5 and IL-10), Flt3 ligand, hematopoietic growth factors (e.g., GM-CSF, SCF), and chemokines (e.g., MIP-1a, MIP-1b, and RANTES). Alternatively, steroids such as methylprednisolone are administrated before or after the pseudovirus or vaccine vector inoculation.

There is no disclosure in either of these passages of the particular combination of Flt3L and MIP-1α. Indeed, these passages do not mention adjuvant combinations at all. As noted above, anticipation requires not only that the prior art document teach each and every claimed element, but that those elements be arranged as required by the claim. Because the '377 patent does not teach the claimed elements arranged as required by the claim, this reference cannot be considered to teach the claimed combination and thus cannot anticipate claim 1 or its dependent claims.

The passages cited by the Office cannot support an anticipation rejection

Applicants have further reviewed each of the passages referenced by the Office in the action (i.e., the abstract; column 1, lines 55-67; column 2, lines 1-29; column 3, lines 19-23; Tables, 1 and 2; columns 16, lines 64-67; column 17, lines 1-10; column 20, lines 65-67; and column 21, lines 1 and 40-49). Other than column 21, lines 40-49, which is discussed above, the only passage that addresses adjuvants is column 3, lines 19-23:

> Also provided are embodiments, wherein at least one of the subunit vaccines further comprise at least one molecular adjuvant selected from the

> group consisting of a co-stimulatory molecule, a cytokine, a chemokine and a growth factor.

At most, this passage suggests the possibility of using more than one molecular adjuvant. There is simply no way to construe this passage as teaching the claimed combination of Flt3L and MIP-1α. Thus, this passage of the '377 patent cannot anticipate claim 1 or its dependent claims.

A generic teaching of "at least one" adjuvant cannot anticipate the claimed combination

Even if the Office were to combine the teachings of column 3, lines 19-23 with those of column 21, lines 40-48 (which Applicants do not concede is proper), the '377 patent still could not be said to teach the claimed combination. The passage from column 3 teaches only that "at least one" adjuvant may be administered. The passage from column 21 teaches adjuvants from six broad classes of agents (co-stimulatory molecules, proinflammatory cytokines, T helper 1 cytokines, T helper 2 cytokines, hematopoietic growth factors, and chemokines), as well as Flt3L. This passage also provides 17 specific examples of agents from these six classes in addition to Flt3L.

The number of possible combinations of "at least one" adjuvant that incorporates these classes of agents is in the hundreds, if not in the thousands, of potential combinations. At most, the '377 patent could be said to teach an extraordinarily broad genus of possible adjuvant combinations.

In the chemical arts, a generic chemical formula is said to anticipate a species when that species can be "at once envisaged" from the formula. M.P.E.P. § 2131.02. Here, the "genus" of adjuvants and adjuvant combinations that could be described by "at least one" adjuvant, includes hundreds or thousands of possible combinations. Only a very small number of these combinations would include the claimed combination. In this situation, the skilled artisan could not at once envisage the particular combination of Flt3L and MIP-1α amongst all possible combinations. Because a genus anticipates a

species only if that species can be at once envisaged from the genus, the '377 patent cannot anticipate claims 1 or its dependent claims.

For all of these reasons, withdrawal of the rejection under 35 U.S.C § 102(e) is respectfully requested.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including June 9, 2011.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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